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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Youngro Byun

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7590

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ALAN J. HOWARTH

P.O. BOX 1909

SANDY, UT 84091-1909

EXAMINER

SELLMAN, CACHET I

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,629	Applicant(s) BYUN ET AL.	
	Examiner CACHET I. SELLMAN	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 1-10, 14 and 16 is/are rejected.
- 7) ☒ Claim(s) 13, 15, 17 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. Claim 17 is an independent form of claim 13. therefore the claims have the same limitation. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

2. Claim 18 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 14. Claim 18 is an independent form of claim 14 therefore the claims have the same limitations. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-12, 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. in view of Bernacca, Tsang et al. (US 5955588).

Ding et al. discloses a process for coating a medical device (i.e. stent) (see col. 4, lines 58-67) with an underlayer (reservoir layer) and a top layer. The coating allows for timed and prolonged pharmacological activity on the surface of the medical device

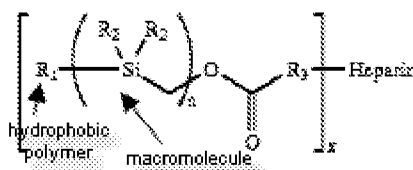
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(see abstract). The reservoir layer comprises a polymer and a biologically active material (see col. 5, lines 31-37). The reservoir layer is formed by combining the polymer and the active agent with a solvent and is then applied to the stent (see example 1). The toplayer comprises an ionic surfactant drug complex which can also contain a polymer (see col. 8, lines 15-30). The drug used in the top layer is heparin (see examples).

Ding et al. fails to teach that the second layer comprises a macromolecule, a hydrophobic material and heparin bound together with covalent bonds, and cleaning the stent with a washing agent as required by **claim 1**.

However, it was well known in the art at the time the invention was made to clean a stent prior to coating in order to remove contaminants and to insure that the coatings will adhere to the stent such as taught by Bernacca et al (US 6251142) therefore one would have been motivated to wash the stent as taught by Bernacca et al. prior to coating in order to ensure sufficient adherence of the coating to the stent.

Tsang et al. teaches a non-thrombogenic coating that is applied to the blood contacting surfaces of medical devices which prevents heparin from leaching out from the coating as a result of breaking of ionic bonds and the covalent bond is not disrupted by the presence of ionic species in the blood that may come in contact (see col. 4 - col. 5). The coating comprises



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Ding et al. to include the top coating comprising the composition of Tsang et al. One would have been motivated to do so because both are directed towards controlled rate release in medical devices especially stents which comprise heparin. Furthermore, Tsang et al. teaches that such a coating improves biocompatibility and high bioactivity which does not easily break or leach out heparin.

The macromolecule can be a biopolymer such as polysaccharide. Heparin is a polysaccharide therefore meeting the requirement of the macromolecule as being a biopolymer.

The underlayer can comprise of more than one drug/ bioactive agent (see col. 7, lines 60-65) as required by **claim 2**. The polymer and agent mixture can be applied by dipping the stent into the mixture or spraying (see col. 7, lines 29-31) as required by **claims 3 and 4**.

As started above, Ding et al. modified by Byun et al. teach the use of the top coating which is used to prevent burst release by adding the rate controlling layer as required by **claim 5**.

As stated above the composition applied to the medical device is an antithrombogenic coating as required by **claim 6**.

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The polymer film can be formed of polyolefins, polyurethanes, silicones, polyesters, polycaprolactones (see col. 5, lines 37-64) as required by **claim 8**. The biologically active agent can be antithrombotic, anticoagulants, antiplatelet, antiinflammatory, antibiotics, etc. (see col. 6, lines 23-40) as required by **claim 9**. The first layer can comprise a second active agent as required by **claim 10**.

The macromolecule can be a synthetic macromolecule such as polysiloxanes as required by **claims 11-12**.

In regards to **claim 14**,

Heparin is a polysaccharide.

Allowable Subject Matter

5. Claim 19 is allowed.
6. Claims 13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1792

/C. I. S./
Examiner, Art Unit 1792

/William Phillip Fletcher III/
Primary Examiner, Art Unit 1792